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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,088	01/22/2001	Mark E. Gurney	PHRM-0303(6225)	5568

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	13

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Fig 6

Office Action Summary	Application No.	Applicant(s)	
	09/767,088	GURNEY ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply* .

DETAILED ACTION

The amendment filed April 25, 2002 (Paper No. 11) has been entered.

Claims 1-17 are pending in the instant application.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Sequences are disclosed in the specification that are not identified by their sequence identifier (i.e., SEQ ID NO:). For example, at page 9, paragraph [0035] of the specification, several PGGG amino acid sequences are referred to, but none are identified by their sequence identifier. **Applicant is reminded that the entire specification and figures should be reviewed for sequence disclosures** and that each sequence disclosed in the specification must be identified by its sequence identifier (i.e., SEQ ID NO:). The specification must be amended to identify all disclosed sequences by their sequence identifier (i.e., SEQ ID NO), in accordance with 37 CFR 1.821(d).

Applicant is given the same shortened statutory period set forth for response to this Office Action within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37

CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human wild-type tau protein, wherein said tau protein is the isoform that is 352 amino acids in length, classified in class 800, subclasses 3 and 18.

II. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human wild-type tau protein, wherein said tau protein is the isoform that is 381 amino acids in length, classified in class 800, subclasses 3 and 18.

III. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human wild-type tau protein, wherein said tau protein is the isoform that is 383 amino acids in length, classified in class 800, subclasses 3 and 18.

IV. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human wild-type tau protein, wherein said tau protein is the isoform that is 410 amino acids in length, classified in class 800, subclasses 3 and 18.

V. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human wild-type tau protein, wherein said tau protein is the isoform that is 412 amino acids in length, classified in class 800, subclasses 3 and 18.

VI. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human wild-type tau protein, wherein said tau protein is the isoform that is 441 amino acids in length, classified in class 800, subclasses 3 and 18.

VII. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human

tau protein, wherein said tau protein is the mutant form encoding the G272V mutation, classified in class 800, subclasses 3 and 18.

VIII. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human tau protein, wherein said tau protein is the mutant form encoding the N279K mutation, classified in class 800, subclasses 3 and 18.

IX. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human tau protein, wherein said tau protein is the mutant form encoding the P301L mutation, classified in class 800, subclasses 3 and 18.

X. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human tau protein, wherein said tau protein is the mutant form encoding the S305N mutation, classified in class 800, subclasses 3 and 18.

XI. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human tau protein, wherein said tau protein is the mutant form encoding the V337M mutation, classified in class 800, subclasses 3 and 18.

XII. Claims 1-17, drawn to a transgenic mouse comprising a polynucleotide encoding a human tau protein, wherein said tau protein is the mutant form encoding the R406W mutation, classified in class 800, subclasses 3 and 18.

Claim 1 links inventions I-XII. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim, claim 1. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application,

the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XII are patentably distinct, one from the other, because the inventions are drawn to distinct compositions and methods of using those compositions. The transgenic mouse of the invention of Group I is structurally, chemically, biologically, and functionally distinct from the transgenic mice of the inventions of Groups II-XII. Each transgenic mouse is made using different starting materials and each has a distinct genotype and would be expected to have a unique phenotype dependent upon the particular underlying genotype. Furthermore, mice with differing genotypes and phenotypes would be expected to give differing results in the drug screening assays. The transgenic animals are not obvious variants. Thus, one transgenic animal would not be considered obvious over any of the others. Therefore, the inventions of Groups I-XII are drawn to mutually exclusive compositions that are patentably distinct, each from the other.

Each of the inventions of Groups I-XII requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the invention of Group I requires consideration of issues relating to the utility and enablement of a transgenic mouse having a wild-type human tau protein of isoform 352 which is separate from the consideration of utility and enablement issues for examination of the invention of Group II, a transgenic mouse having a mutant form of human tau protein comprising the G272V mutation. Furthermore, the searches for the

inventions of Groups I-XII are not coextensive. Thus, search and examination of all 12 inventions in a single patent application constitutes a serious burden on the Examiner.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Application No.: 09/767,088

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: The specification and/or figures must be amended to identify all disclosed sequences by their sequence identifier (i.e., SEQ ID NO), in accordance with 37 CFR 1.821(d).

Applicant Must Provide:

- [ ] An **initial** computer readable form (CRF) copy of the "Sequence Listing".
- [ ] An **initial** paper copy of the "Sequence Listing", **as well as an amendment directing its entry into the specification.**
- [ ] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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